IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

VISION BIOSYSTEMS (USA) TRADING, INC.,

Plaintiff,

v.

CIVIL ACTION NO. 03-CV-10391-GAO

VENTANA MEDICAL SYSTEMS, INC.,

Defendant.

VENTANA MEDICAL SYSTEMS, INC.,

Plaintiff,

v.

CIVIL ACTION NO. 05-CV-10614-GAO

VISION BIOSYSTEMS, INC.,

Defendant.

JOINT STATUS REPORT, STIPULATION AND [PROPOSED] ORDER

Ventana Medical Systems, Inc. and Vision BioSystems, Inc. respectfully submit this Joint Status Report, Stipulation and Proposed Order.

The parties previously submitted a Stipulation and Proposed Scheduling Order (Docket No. 47 in 05-CV-10614) that proposed certain discovery deadlines triggered by the issuance of the opinion of the United States Court of Appeals for the Federal Circuit, in *Ventana Medical Systems, Inc. v. BioGenex Laboratories, Inc.*, Case No. 06-1074 ("the BioGenex Appeal"). The Federal Circuit issued an opinion in the BioGenex Appeal on December 29,

2006, but has not yet issued its mandate. See Exhibit A hereto. The mandate will issue after any further proceedings on appeal (e.g., petition for rehearing) are completed or after the time for such proceedings expire, and when jurisdiction may be regained by the District Court.

The parties have concluded that a further case schedule should not be adopted until the Federal Circuit issues its mandate. Issuance of the mandate will provide greater certainty as to the effect that the BioGenex Appeal may have on this litigation. Therefore, the parties believe that further proceedings would be most efficiently conducted under a revised schedule.

IT IS HEREBY STIPULATED by the parties to this action, subject to the order of the Court, that any outstanding scheduling deadlines are vacated. Within 21 days of issuance of the mandate in the BioGenex Appeal, the parties shall file a Joint Proposed Scheduling Order. proposing dates for subsequent deadlines in this litigation. If the parties cannot agree on proposed dates, the Joint Proposed Scheduling Order shall set forth the parties' respective proposals.

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SO ORDERED this _____ day of January, 2007.

George A. O'Toole, Jr. United States District Judge

United States Court of Appeals for the Federal Circuit

06-1074

VENTANA MEDICAL SYSTEMS, INC.,

Plaintiff-Appellant,

٧.

BIOGENEX LABORATORIES, INC.,

Defendant-Appellee.

Ron E. Shulman, Wilson Sonsini Goodrich & Rosati, of Palo Alto, California, argued for plaintiff-appellant. With him on the brief were Roger J. Chin, and Nicole W. Stafford, of Austin, Texas.

<u>Peter B. Goldman</u>, Leonard Felker Altfeld Greenberg & Battaile, P.C., of Tucson, Arizona, argued for defendant-appellee. With him on the brief were <u>Jeffrey H. Greenberg</u> and <u>Lorenzo B. Cellini</u>.

Appealed from: United States District Court for the District of Arizona

Judge Raner C. Collins

United States Court of Appeals for the Federal Circuit

06-1074

VENTANA MEDICAL SYSTEMS, INC.,

Plaintiff-Appellant,

٧.

BIOGENEX LABORATORIES, INC.,

Defendant-Appellee.

DECIDED: December 29, 2006

Before LOURIE, DYK, and PROST, Circuit Judges.

Opinion for the court filed by <u>Circuit Judge</u> PROST. Dissenting opinion filed by <u>Circuit Judge</u> LOURIE.

PROST, Circuit Judge.

Plaintiff-Appellant, Ventana Medical Systems, Inc. ("Ventana") appeals the decision of the United States District Court for the District of Arizona granting judgment of noninfringement of U.S. Patent No. 6,352,861 (the "861 patent") in favor of Defendant-Appellee, BioGenex Laboratories, Inc. ("BioGenex"). Because the district court erred in its claim construction, we vacate the judgment of noninfringement and remand for further proceedings.

BACKGROUND

Ventana is the owner of several patents relating to automated methods and apparatuses for staining microscope slides. Such methods and apparatuses may be used, for example, to detect diseases in the tissues of patients. In a process known as immunostaining, pathologists first mount tissue samples on microscope slides. The slides then undergo a series of treatment steps including the application of various reagents such as antibody stains. Each of these treatment steps is separated by multiple rinse steps, during which unreacted reagents are removed from the slides. Finally, the stained slides are examined by pathologists to detect the presence of diseases.

At issue in this case is Ventana's '861 patent, entitled "Automated Biological Reaction Apparatus." As the title suggests, the '861 patent claims automated apparatuses and methods used to perform a variety of biological assays, including immunostaining. The '861 patent stems from the same original patent application as six other patents assigned to Ventana: U.S. Patent No. 5,595,707 (the "'707 patent"); U.S. Patent No. 5,650,327 (the "327 patent"); U.S. Patent No. 5,654,199 (the "199 patent"); U.S. Patent No. 5,654,200 (the "'200 patent"); U.S. Patent No. 6,827,901 (the "'901 patent"); and U.S. Patent No. 6,943,029 (the "'029 patent"). All seven of these patents share a common specification. The common specification discusses various previously known automated staining devices and asserts that such prior art devices "are limited in their performance and unable to satisfy the needs for automated, high precision immunohistology." '861 patent, col. 2, Il. 26-28. To overcome these problems, the inventors of this family of patents sought to

provide a device which provides more rapid, reliable and more reproducible results than standard methods; can perform any standard immunochemical assay . . . ; preforms [sic] all steps of the immunohistochemical assay irrespective of complexity or their order, at the time and temperature, and in the environment needed; and is cost effective in terms of equipment, reagent and labor costs.

'861 patent, col. 2, II. 29-38.

The common specification discloses an automated slide staining apparatus possessing multiple features, and each of Ventana's seven patents claims various combinations of these features and methods related to these features. For example, the '327 patent is entitled "Method for Mixing Reagent and Sample Mounted on a Slide" and the claims relate to methods that use streams of gas to stir the reagents on the slide surface. In contrast, the claims of the '861 patent relate to automated dispensing systems that employ bar code-labeled reagent containers and/or slides. As described in the patent specification,

[b]ar code reader 231 (FIG. 14) above slide 205 reads a slide bar code 233 (FIGS. 13 and 17) on each slide. The slide bar codes [sic] 233 identifies the slide sample and the particular immunohistochemical process required for that sample. This information is fed into the computer and correlated with the indexed position of that slide with respect to "home", to control the sequence of reagent chemicals to be applied to that slide in the reagent application zone.

'861 patent, col. 9, II. 48-55. The specification further discloses that the reagent containers may also be labeled with bar codes:

A reagent bar code reader 346 can be mounted on post 302, positioned to scan a reagent bar code 348 on the reagent bottle 12. Bar code 348 identifies the contents of the reagent bottle. At the beginning of a slide treatment operation, the reagent carousel 10 is rotated past the bar code reader 346, and the bar code 348 on each reagent bottle 12 is scanned. The scanned information is fed to the computer and correlated with the indexed position of the reagent carousel 10. This information is used to rotate the reagent carousel 10 to place the correct reagent bottle 12 in the application zone for each slide treatment step for each slide.

<u>Id.</u>, col. 12, Il. 28-38.

BioGenex manufactures and sells automated staining devices. On February 11, 2003. Ventana filed suit against BioGenex alleging infringement of claims 1, 2, 3, 5, 6, and 8 of the '861 patent. The district court held a Markman hearing and construed certain disputed claim terms in a written opinion. Ventana Med. Sys., Inc. v. BioGenix [sic] Labs., Inc., No. 03-CV-92, slip op. at 1-17 (D. Ariz. Aug. 23, 2005) ("Claim" Construction Order"). In light of the district court's construction of the claim term "dispensing," which appears in all of the asserted claims, Ventana stipulated to a judgment of noninfringement and reserved its right to appeal the district court's claim construction. Accordingly, the district court entered a final judgment of noninfringement. Ventana Med. Sys., Inc. v. BioGenex Labs., Inc., No. 03-CV-92, slip op. at 1-2 (D. Ariz. Oct. 4, 2005). Ventana now appeals.

DISCUSSION

The sole issue on appeal is the proper construction of the claim term "dispensing" in asserted claims 1, 2, 3, 5, 6, and 8 of the '861 patent. Of the asserted claims, claims 1 and 5 are independent. Both cover "[a] method of dispensing reagents onto a slide." Claim 1 reads:

1. A method of dispensing reagents onto a slide, the method comprising the steps of:

providing at least one reagent container;

providing at least one slide on a slide support:

automatically identifying the reagent container using a computer;

automatically determining whether reagent in the reagent container should be dispensed onto the slide; and

dispensing the reagent in the reagent container onto the slide based on the determination of whether the reagent in the reagent container should be dispensed onto the slide,

wherein the step of automatically determining whether reagent in the reagent container should be dispensed onto the slide includes the steps of:

providing a bar code reader;

reading a slide bar code placed on the slide using the bar code reader thereby acquiring slide information, the slide information indicating reagents to be applied to the slide; and

sending the slide information to the computer.

'861 patent, col. 24, l. 53 - col. 25 l. 6 (emphases added). And claim 5 reads:

5. A method of dispensing reagents onto a slide, the method comprising the steps of:

providing a plurality of reagent containers in a reagent support, each of the reagent containers having a reagent barcode;

providing at least one slide on a slide support, the slide having a bar code; providing a bar code reader;

reading the bar codes on the reagent containers;

determining reagents in the reagent containers based upon the reading of the bar codes on the reagent containers;

reading the slide bar code on the at least one slide:

determining a sequence of reagents to be applied on the at least one slide based upon the reading of the slide bar code on the slide; and

dispensing the reagents in the reagent containers based upon the sequence of reagents to be applied.

'861 patent, col. 25, Il. 18-36 (emphases added).

The district court construed the "dispensing" claim limitation to require "direct dispensing," meaning that "the reagent is dispensed directly from the reagent container" onto the slide, rather than utilizing an intermediate transport mechanism to transfer reagent from the reagent container to the slide. Claim Construction Order, slip op. at 5-7. The district court held that the context in which the "dispensing" term is used in the claim "necessitates 'direct dispensing' by stating that the reagent in the reagent container is dispensed onto the slide, meaning the reagent is dispensed directly from the reagent container." Id., slip op. at 6. The district court also noted that the written description and figures supported a narrow construction of "dispensing" because all of

the disclosed embodiments dispense reagent directly from the bottom of the reagent container without using any intermediate transfer device. Id., slip op. at 7.

After construing the term "dispensing" to mean "direct dispensing," the district court held that the inventors disclaimed a particular type of dispensing, "sip and spit" dispensing, during the prosecution of an ancestor application. In "sip and spit" dispensing, an intermediate transport mechanism such as a pipette uses suction to "sip" the reagent from the reagent container and then releases or "spits" the reagent onto the slide. The '861 patent issued from a continuation of a continuation of a division of a continuation of U.S. Patent Application No. 07/924,052 (the "052 application"), which originally presented 93 claims. Independent claim 1 of the '052 application provided:

1. A biological reaction apparatus for dispensing a selected reagent directly to a sample, said biological reaction apparatus having:

a reagent carousel having a plurality of reagent container supports thereon:

homing and indexing means, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position; and

drive means, engaging the reagent carousel and operatively coupled to said homing and indexing means, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone wherein said reagent supply zone is oriented so that a reagent in a container in said preselected reagent container support is dispensable directly to a sample.

(emphases added). The examiner rejected independent claim 1 and dependent claims 2-3 and 5-6 of the '052 application under 35 U.S.C. § 103 as being unpatentable over two prior art references, Wakatake et al. and Assmann et al. In response, the inventors argued that neither the Wakatake nor the Assmann reference disclosed the capability to dispense reagent "directly to a sample":

The six patents that share a common disclosure with the '861 patent are all descendants of the '052 application.

[E]ven in the unlikely event that Wakatake and Assmann were successfully combined into one system, the resulting system would still lack the present invention's novel capability to dispense reagent "directly to a sample" as set forth in Applicants' Claim 1, at line 16.

. . . [T]he recited apparatus provides for direct dispensing of reagent from a reagent container to a sample. . . . The present invention uses the "drive means" to rotate the "reagent carousel." The reagent carousel holds the reagent containers. As can be seen in the Figures, the Reagent carousel is positioned above the samples and the reagent containers are oriented within the carousel with their outlet nozzles pointing down such that they are ready to dispense reagent directly to the sample below. . . .

In contrast, Wakatake et al teaches reagent tables positioned side by side with a reaction table. (Wakatake et al, Figure 2). This side by side configuration precludes dispensing of the reagent "directly to a sample" or the incorporation of a "reagent delivery zone" as set forth in Claim 1 of the present invention. The Wakatake side by side configuration requires an additional device, a reagent pipetting device, to transfer the reagent between tables and mediate the dispensing of reagent to the sample. The reagent pipetting device is used to suck up an aliquot of reagent from a reagent container on one of at least two reagent tables, pivot so that the pipetting tube of the device is held just above a selected reaction vessel on a separate reaction table, and dispense the aliquot of reagent to the vessel (Wakatake at column 4, line 42 to column 5, line 10). Such devices are referred to in the trade as "sip and spit" devices.

The district court held that these statements during prosecution amounted to a "clear and unmistakable" disclaimer of "sip and spit" dispensing from claim 1 of the '052 application. Claim Construction Order, slip op. at 11. The district court further held that this disclaimer attached to claims 1 and 5 of the '861 patent

because there is a common claim limitation to which the disclaimer is directed: "direct dispensing." The court has already construed the claim term "dispensing" in the '861 patent to mean "direct dispensing" and thus, the '052 application and '861 patent have the same claim limitation. The "sip and spit" disclaimer may properly attach to the '861 patent (direct) dispensing limitation.

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This court reviews claim construction de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). On appeal, Ventana argues that the district court improperly limited the scope of the term "dispensing" to cover only those methods of dispensing in which the reagent container is also the reagent dispenser (i.e., "direct dispensing"). Accordingly, Ventana asks this court to reverse the district court's claim construction and construe the phrase "dispensing" to mean "to apply reagent to the slide." We agree that the district court improperly imported limitations from the specification when it construed the term "dispensing" to require "direct dispensing."

Claim terms "are generally given their ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). And "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art." Id. at 1313. In this case, Ventana argues that there is nothing in the record to suggest that a person of ordinary skill in the art would interpret the disclosure and claims of the '861 patent to mean that the term "dispensing" is limited to "direct dispensing." We agree.

To start with, claims 1 and 5 do not contain any language that could be read to limit the term "dispensing" to require "direct dispensing." Although "direct dispensing" is one type of dispensing, BioGenex does not appear to dispute that other types of dispensing, such as "sip and spit" dispensing, also fall within the ordinary meaning of "dispensing." Though the district court held that the word "onto" in the language of the claim necessitated "direct dispensing" because the claims require that reagent in the

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reagent container be dispensed "onto" the slide, BioGenex agreed at oral argument that the word "onto" does not by itself exclude the "sip and spit" method of dispensing from the ordinary meaning of "dispensing."

Instead, BioGenex argues that the patent's specification compels a narrow construction of "dispensing." BioGenex first points to the "BACKGROUND ART" section of the patent, which discusses a number of prior art automated staining devices, including a device that BioGenex alleges employs the "sip and spit" method of dispensing. '861 patent, col. 2, II. 6-16. BioGenex argues that because the patent goes on to state that "[t]he previously known devices are limited in their performance and unable to satisfy the needs for automated, high precision immunohistology" and that it was an object of the invention to "provide a device which provides more rapid, reliable and more reproducible results than standard methods," <u>id.</u> at col. 2, II. 26-31, the patent makes clear that the invention does not practice the "sip and spit" method of dispensing.

We decline to interpret these general statements by the inventors to effect a complete surrender from the claims of the '861 patent of all types of dispensing except "direct dispensing." For one thing, the "BACKGROUND ART" section includes discussion of a number of different prior art devices that employ a number of different dispensing techniques, including a device that employs a "direct dispensing" technique. Id. at col. 1, I. 65 - col. 2, I. 5 ("Stark, E. et al, J.Immunol.Methods. 107:89-92 (1988) describes a microprocessor controlled system including a revolving table or carousel supporting radially positioned slides. A stepper motor rotates the table, placing each slide under one of the stationary syringes positioned above the slides. A predetermined volume of liquid, determined by a dial, is delivered to a slide from each syringe."). Thus,

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if BioGenex's argument were correct, the inventors have also disavowed coverage of "direct dispensing," which is the type of dispensing employed by the patent's preferred embodiment. For this reason, BioGenex's argument cannot be correct.

Moreover, this is not a case in which the inventor's distinguishing the invention over the prior art in the specification results in a disavowal of coverage by the inventor of features in the prior art. In Phillips, we recognized that in certain cases, "the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." Phillips, 415 F.3d at 1316. In such cases, this court interprets the claim more narrowly than it otherwise would to give effect to the inventor's intent to disavow a broader claim scope. Id.; Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1319-20 (Fed. Cir. 2006); SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1342-44 (Fed. Cir. 2001). Here, however, BioGenex points to only general statements by the inventors indicating that the invention is intended to improve upon prior art automated staining methods: "The previously known devices are limited in their performance and unable to satisfy the needs for automated, high precision immunohistology. It is an object of this invention to provide a device which provides more rapid, reliable and more reproducible results than standard methods " '861 patent, col. 2, II. 26-31. Such general statements, without more, will not be interpreted to disclaim every feature of every prior art device discussed in the "BACKGROUND ART" section of the patent.

Next, BioGenex points out that all of the '861 patent's disclosed embodiments employ a "direct dispensing" method of dispensing. BioGenex submits that when the specification is read in its entirety, one of skill in the art would come to the "inescapable

conclusion that the novelty of Ventana's invention is the birthday cake or over/under carousel arrangement for direct dispensing." As a result, BioGenex argues, the specification has implicitly defined the term "dispensing" to mean "direct dispensing."

There are, however, several problems with this argument. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips, 415 F.3d at 1312 (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "[A]Ithough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." Id. at 1323. While the fact that the disclosed embodiments are limited can assist in interpreting claim language, the mere fact that the '861 patent discloses embodiments in which the reagent container is also the reagent dispenser does not in and of itself mean that the method claims at issue are limited to the disclosed embodiments.

The second problem with BioGenex's argument is that each claim does not necessarily cover every feature disclosed in the specification. When the claim addresses only some of the features disclosed in the specification, it is improper to limit the claim to other, unclaimed features. Id. at 1327; see also Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331 (Fed. Cir. 2004) ("[P]atentees [are] not required to include within each of their claims all of [the] advantages or features described as significant or important in the written description."); E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1370 (Fed. Cir. 2003) ("An invention may possess a number of advantages or purposes, and there is no requirement that every claim directed to that

invention be limited to encompass all of them."). Here, the claims of the '861 patent are directed toward automated methods of dispensing that use bar codes to determine which reagents should be dispensed onto which slides. Although the preferred embodiments also contain a "direct dispensing" feature, the inventors were not required to claim this feature in the '861 patent and, indeed, did not do so.

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Ventana also argues that the district court erred in holding that the inventors of the '861 patent disclaimed coverage of "sip and spit" dispensing during prosecution of the '052 application, an ancestor of the '861 patent. BioGenex responds that the inventors disclaimed "sip and spit" dispensing when they distinguished the prior art "sip and spit" devices because of those devices' inability to dispense reagent "directly to a sample," as required claim 1 of the '052 application.

BioGenex thus raises the doctrine of prosecution disclaimer. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317. Accordingly, we examine the patent's prosecution history, when placed in evidence, to determine whether the inventor disclaimed a particular interpretation of a claim term during the prosecution of the patent in suit or during the prosecution of an ancestor application. Id.; Advanced Cardiovascular Sys. v. Medtronic, Inc., 265 F.3d 1294, 1305-06 (Fed. Cir. 2001). But the doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language. Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1078 (Fed.

Cir. 2005) ("[T]he prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application."); ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1383 (Fed. Cir. 2003) ("Although a parent patent's prosecution history may inform the claim construction of its descendant, the [parent] patent's prosecution history is irrelevant to the meaning of this limitation because the two patents do not share the same claim language."); Advanced Cardiovascular Sys., 265 F.3d at 1305-06.

In this case, the allegedly disclaiming statements were made with respect to claim language that expressly required reagent in the reagent container to be "dispensable directly to a sample." Indeed, in distinguishing the prior art, the inventors stated that the prior art "sip and spit" devices lacked "the present invention's novel capability to dispense reagent 'directly to a sample' as set forth in Applicants' Claim 1, at line 16" (emphasis added). Because claims 1 and 5 of the '861 patent use different claim language—that is, they do not require that reagent be "dispensable directly to a sample"—the alleged disclaimer of "sip and spit" dispensing during the prosecution of the '052 application does not apply to the asserted claims of the '861 patent.²

BioGenex makes a number of arguments in response to a perceived argument by Ventana that a disclaimer made during prosecution of the '052 application does not apply to the claims of the '861 patent because the '861 patent resulted from a divisional application as opposed to a continuation application. We do not understand Ventana to be making this argument, however, so we need not address BioGenex's responses to it. Regardless of whether the '861 patent resulted from a divisional application or a continuation application, the alleged disclaimer of "sip and spit" dispensing does not apply to the asserted claims of the '861 patent because claim 1 of the '052 application and the asserted claims of the '861 patent do not share a common claim term in dispute.

Indeed, we agree with Ventana that the prosecution history of the '861 patent supports a broad construction of "dispensing." For example, during the prosecution of the application that led to the '861 patent, the examiner issued a restriction requirement. With respect to the application claims that eventually resulted in claims 1 and 5 of the '861 patent, the examiner observed that "the process as claimed can be practiced by another materially different apparatus or by hand, such as a manual pipette means." This statement shows that the patent examiner did not consider the "dispensing" claim term to be limited to the "direct dispensing" embodiment disclosed in the specification. Moreover, the inventors did not rely on "direct dispensing" as a distinction between the claims at issue in this case and the prior art. Instead, in response to rejections over the prior art, the inventors limited their arguments to the ability of the claimed inventions to address the shortcomings of manual reagent identification and manual determination of reagent dispensing protocols.

IV

BioGenex next argues that the inventors disclaimed "sip and spit" dispensing from claims 1 and 5 of the '861 patent during the prosecution of two later-issued patents, the '901 patent and the '029 patent. The district court did not address the relevance, if any, of the prosecution histories of the '901 and the '029 patents in its claim construction opinion. Nevertheless, for the reasons described below, we agree with Ventana that the prosecution histories of these later patents do not inform the proper construction of "dispensing" in claims 1 and 5 of the '861 patent.

The '861 patent issued from U.S. Patent Application No. 09/452,309 (the "'309 application"). Each of the later-issued patents resulted from continuations of the '309

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application.³ Independent claim 72 of the '169 application (which issued as claim 1 of the '901 patent) provided, in part:

- 72. A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising: a reagent carousel having a plurality of reagent container supports thereon:
- a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;

[and] a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide

(emphases added).

In responding to a obviousness rejection of application claim 72 and its corresponding dependent claims, the inventors distinguished a prior art "sip and spit" reference because it transferred reagents "by pipettes into cuvettes 106 held in sample analysis carousels 102 that are adjacent to and not below the reagent carousel" as required by the claims. In distinguishing another prior art reference, the inventors stated that

the invention of claim 72 et al. includes a sample carousel arranged beneath a reagent carousel [and] the reagent is dispensed onto a slides [sic] position below the reagent carousel. . . .

Locating the carousel including samples containing slides below the reagent carousel is an important feature of the claimed invention because it allows the reagent to be applied directly to the samples on the slides.

The '901 patent issued from U.S. Patent Application No. 10/137,169 (the "169 application"), which was a continuation of a continuation of the '309 application. The '029 patent issued from U.S. Patent Application No. 10/054,535 (the "'535 application"), which was a continuation of the '309 application.

BioGenex asserts that these statements amount to a disclaimer of "sip and spit dispensing" that should be applied to the claims of the '861 patent.

We have held that statements made by the inventor during continued prosecution of a related patent application can, in some circumstances, be relevant to claim construction. See Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349 (Fed. Cir. 2004) (recognizing that "the prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application"). As with statements made by the inventor during the prosecution of an ancestor application, statements made during the continued prosecution of a sibling application may "inform the meaning of the claim language by demonstrating how the inventor understood the invention." Phillips, 415 F.3d at 1317.

But here, once again, BioGenex points to statements made with respect to claim language that expressly required the reagent to be "dispensable from a lower end of [the] container onto the slide." Because claims 1 and 5 of the '861 patent do not contain this claim language, these statements are not relevant to the construction of "dispensing" in claims 1 and 5 the '861 patent.

Similarly unpersuasive is BioGenex's assertion that the inventors disclaimed "sip and spit" dispensing during prosecution of the '029 patent. Independent claim 92 of the '535 application (which issued as claim 17 of the '029 patent) called for "a method of dispensing reagents onto a slide" where the reagent container and the slide support are moved "relative to one another to position the reagent container over the slide." In response to an obviousness rejection, the inventors distinguished a prior art "sip and spit" device because it positioned the reagent containers adjacent to the receptacles

into which the reagents were dispensed. Thus, the prior art device did not position the reagent container "over the slide," as required by the claim. Claims 1 and 5 of the '861 patent, however, do not contain this language. Consequently, the statements pointed to by BioGenex are not relevant to the construction of "dispensing" in claims 1 and 5 the '861 patent.4

CONCLUSION

Because the district court erred in its construction of "dispensing," we vacate the judgment of noninfringement and remand for further proceedings.

COSTS

Each party shall bear its own costs.

VACATED AND REMANDED

BioGenex also points out that the patent examiner issued an obviousnesstype double patenting rejection of all of the claims of the '535 application over the claims of the '861 patent. The inventors responded to the obviousness-type double patenting rejection by filing a terminal disclaimer. BioGenex argues that the filing of the terminal disclaimer represents an admission by the inventors "equating all claims of the '535 application to all claims of the '861 Patent." As a result of the terminal disclaimer, BioGenex argues, any prosecution disclaimer of "sip and spit" dispensing in the '535 application applies to the claims of the '861 patent. We disagree. For one thing, "the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection." Quad Envtl. Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 874 (Fed. Cir. 1991). Moreover, the inventors' filing of a terminal disclaimer does not change the fact that the asserted claims of the '861 patent do not contain the "over the slide" limitation present in claim 92 of the '535 application. As a result, arguments made during prosecution of the '535 application with respect to whether the prior art "sip and spit" devices positioned the reagent container "over the slide" are irrelevant to the construction of "dispensing" in claims 1 and 5 of the '861 patent.

United States Court of Appeals for the Federal Circuit

06-1074

VENTANA MEDICAL SYSTEMS, INC.,

Plaintiff-Appellant,

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BIOGENEX LABORATORIES, INC.,

Defendant-Appellee.

LOURIE, Circuit Judge, dissenting.

I respectfully dissent from the majority's decision to vacate and remand based upon its construction of the term "dispensing." I believe that the district court correctly construed the disputed term in light of the specification and, for that reason, I would affirm.

"[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Id. at 1315 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). When read in the context of the specification, the claim term "dispensing" clearly means "direct dispensing."

The '861 patent is part of a family of six other patents sharing a common specification, although only claim 15 of the '707 patent expressly recites "direct dispensing." Claim 1 of application 07/924,052, which eventually was abandoned, was amended to include the word "direct dispensing" in order to overcome prior art. Claim 1 of the '861 patent is broader and makes no reference to dispensing directly. Nonetheless, the claims must be construed in light of the specification, which is the same for all seven patents and which repeatedly describes dispensing reagent directly from a reagent container onto a slide.

The Summary of the Invention describes "positioning a preselected reagent container support and associated reagent container in a reagent supply zone. The apparatus has a reagent delivery actuator means positioned for engaging a reagent container positioned on a container support in the reagent supply zone and initiating reagent delivery from the reagent container to a slide supported on a slide support in the reagent receiving zone." '861 patent, col. 2, II. 53-59. The Summary further describes using a "volumetric pump means, and a reagent delivery actuator means positioned for activating the volumetric pump means, thereby effecting delivery of reagent from a reagent container by the volumetric pump to the reagent delivery zone." '861 patent, col. 3, II. 53-56. Those statements of delivery from a reagent container to a slide describe direct dispensing. They describe the essence of the invention and clearly show that the reagent is dispensed directly from a reagent container positioned in a support onto a slide.

Such statements are repeated throughout the rest of the specification. For example, in the Detailed Description of the Invention, the specification describes that

"[t]he carousel 10 is rotated by the stepper motor 14 drive belt 16 to a position placing a selected reagent bottle 12 in the reagent delivery position under the air cylinder reagent delivery actuator 18 over a slide to be treated with reagent." '861 patent, col. 6, II. 54-57. The specification further indicates that the "reagent delivery actuator 18, supported by support arm 216, contacts reagent bottle 218, directly over slide 214." '861 patent, col. 9, II. 24-26 (emphasis added). The text accompanying Figure 15 describes the dispensing: "Delivery of pressurized air to the cylinder 18 causes rod 304 and its attached foot 306 to move downward against a reagent container 12 positioned in the reagent delivery zone. Downward movement of reagent container 12 causes emission of a precise volume of reagent liquid 310." '861 patent, col. 11, II. 40-45. Finally, Figures 1, 2, 3, 4, 11, 15 depict the apparatus that employs direct dispensing. The figures depict reagent containers in a carousel placed directly over a slide to dispense the reagent from the container onto the slide.

Statements describing dispensing reagent directly from a reagent container onto a slide are thus found in the abstract, the summary of the invention, the detailed disclosure of the invention, and the figures. Those statements do not merely describe a preferred embodiment of the invention; they broadly disclose the overall invention of all seven patents. The majority points out that, because the preferred embodiment discloses direct dispensing, we should not limit the claims to only that which is the disclosed embodiment. However, this is not a case of limiting the claims by looking at a preferred embodiment. Direct dispensing is the essence of the invention, and the specification supports that conclusion. The specification, shared by all seven patents, leads to the "inescapable conclusion" that the invention of the '861 patent consists of

"direct dispensing." Microsoft Corp. v. Mult-Tech Sys., Inc., 357 F.3d 1340, 1348 (Fed. Cir. 2004) (citing SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1342 (Fed. Cir. 2001)). Moreover, nowhere does the specification suggest that the invention includes the alternative "sip and spit" dispensing method, involving dispensing reagent from an upright container by means of a pipette. Accordingly, I believe that the district court correctly construed the claims to require "direct dispensing."

An examination of the prosecution history confirms that Ventana viewed its inventions as limited to direct dispensing. In a related grandparent application, in order to overcome an examiner's rejection, Ventana argued that the prior art lacked the "present invention's novel capability to dispense reagent 'directly to a sample" and that the "apparatus of the present invention" uses a reagent carousel and reagent container supports, "which minimize the time required to apply a given reagent, and the time between the application of multiple reagents, by dispensing reagent 'directly to a sample." Ventana further stated: "As can be seen in the Figures, the reagent carousel is positioned above the samples and the reagent containers are oriented within the carousel with their outlet nozzles pointing down such that they are ready to dispense reagent directly to the sample below." Those statements made in the prosecution of the related patent application, having the same specification, reflect that Ventana understood its own invention to be limited to direct dispensing. We cannot construe the claims to cover subject matter broader than that which the patentee described in its specification, regarded as comprising its invention, and represented to the Patent and Trademark Office.

Even though those statements from the prosecution were made in a grandparent patent application, they relate to the common specification and reflect Ventana's own understanding of its invention. I believe, therefore, that the statement in the prosecution of the '052 application is indicative of the proper interpretation of the same claim term in the later-issued '861 patent.

In sum, the district court appropriately considered the specification and related prosecution history and determined the ordinary meaning of "dispensing" in light of all the intrinsic evidence. I see no error in the court's approach or result. Accordingly, I would affirm the district court's claim construction.